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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/645,554	08/22/2003	Yoshinao Nagashima	240945US0DIV	8690

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EXAMINER

CHANNAVAJALA, LAKSHMI SARADA

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 07/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/645,554

Applicant(s)

NAGASHIMA ET AL.

Examiner

Lakshmi S. Channavajjala

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 May 2005.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 16-19 and 21-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 16-19 and 21-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Receipt of amendment and remarks dated 5-12-05 is acknowledged.

Claims 16-19 and 21-23 are pending.

Response to Arguments

Applicant's arguments with respect to claims 16-19 and 21-23 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 103

Claims 16-18 and 21-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,302,522 to Takigawa et al ('522).

'522 teach a process for the production of a sesquiterpene alcohol, cedrenol, from the microorganism belonging to the genus *Rhodococcus* (col.1, lines 67 through col.2, lines 30). '522 teach that the process results in high yield and high purity of cedrenol (col. 6, lines 25-33). '522 do not teach the claimed lotion, emulsion and pharmaceutical preparations. '522 also lack the limitation of percentage and the odor level. However, '522 suggest the use of cedrenol in cosmetics and pharmaceuticals owing to its skin care and vasodilatory function respectively. '522 also suggests using cedrenol in bathing preparations. Therefore, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention to use cedrenol of '522 in any suitable form i.e., a lotion, emulsion etc., and use for cosmetic care or a pharmaceutical application. Further, '522 do not mention employing cedrenol at a level that has detectable or not and therefore, absent evidence as to criticality, it would have been

Art Unit: 1615

within the scope of a skilled artisan to optimize the amount of cedrenol in the formulation depending the effect i.e., cosmetic or pharmaceutical, desired.

Claims 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,302,522 to Takigawa et al ('522) in view of US 4,254,145 to Birnbaum ('154).

'522 suggest using cedrenol for pharmaceutical application but fail to teach the components of claim 19.

'154 teach pharmaceutical composition for the treatment of vasodilation employing active agents such as prostaglandins, with vasodilator activity (col. 5, lines 5-32). '145 suggest employing various pharmaceutical carriers for efficient delivery of the vasodilator compounds, which include the claimed glycols, emulsifiers, oils etc. Thus, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention that the claimed oils, glycols etc., are conventionally known pharmaceutical carriers for effective delivery of pharmaceutical vasodilator compounds. Therefore, a skilled artisan preparing a pharmaceutical vasodilator product of '522 would have been motivated to use the conventional pharmaceutical carriers such as those of '145 with an expectation to provide an effective delivery of cedrenol and hence the desired vasodilation effect.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

Art Unit: 1615

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S. Channavajjala whose telephone number is 571-272-0591. The examiner can normally be reached on 9.00 AM -6.30 PM

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.


Art Unit: 1615

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Lakshmi S Channavajjala
Examiner
Art Unit 1615

July 13, 2005



THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600